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(54) **MEDICAL DEVICE GUIDEWIRE WITH HELICAL CUTOUT AND COATING**

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(52) **U.S. Cl.**

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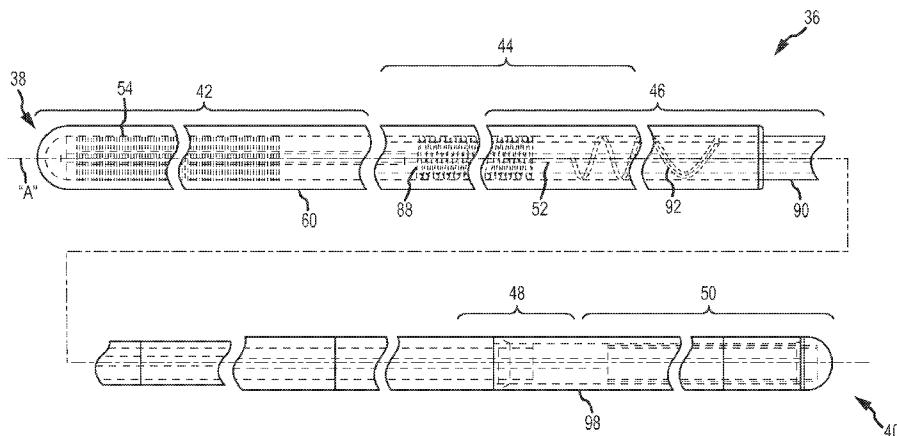
ABSTRACT

A guidewire for a medical device is disclosed. The guidewire includes an elongate body, a proximal connector assembly, a corewire, and a sensor assembly. The body has an annular wall that defines an interior lumen. The proximal connector assembly is coupled to the body and is configured for connection to a medical positioning system. The corewire extends through the lumen. The sensor assembly located on a distal end of the corewire is electrically connected to the proximal connector assembly. The sensor assembly is configured to generate an electrical signal indicative of a position of the sensor assembly in a reference coordinate system defined in the medical positioning system. The body includes a helical cutout extending over a predetermined length of the body. The helical cutout is configured to increase the flexibility over the predetermined length of the body.

(58) **Field of Classification Search**

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See application file for complete search history.

20 Claims, 8 Drawing Sheets



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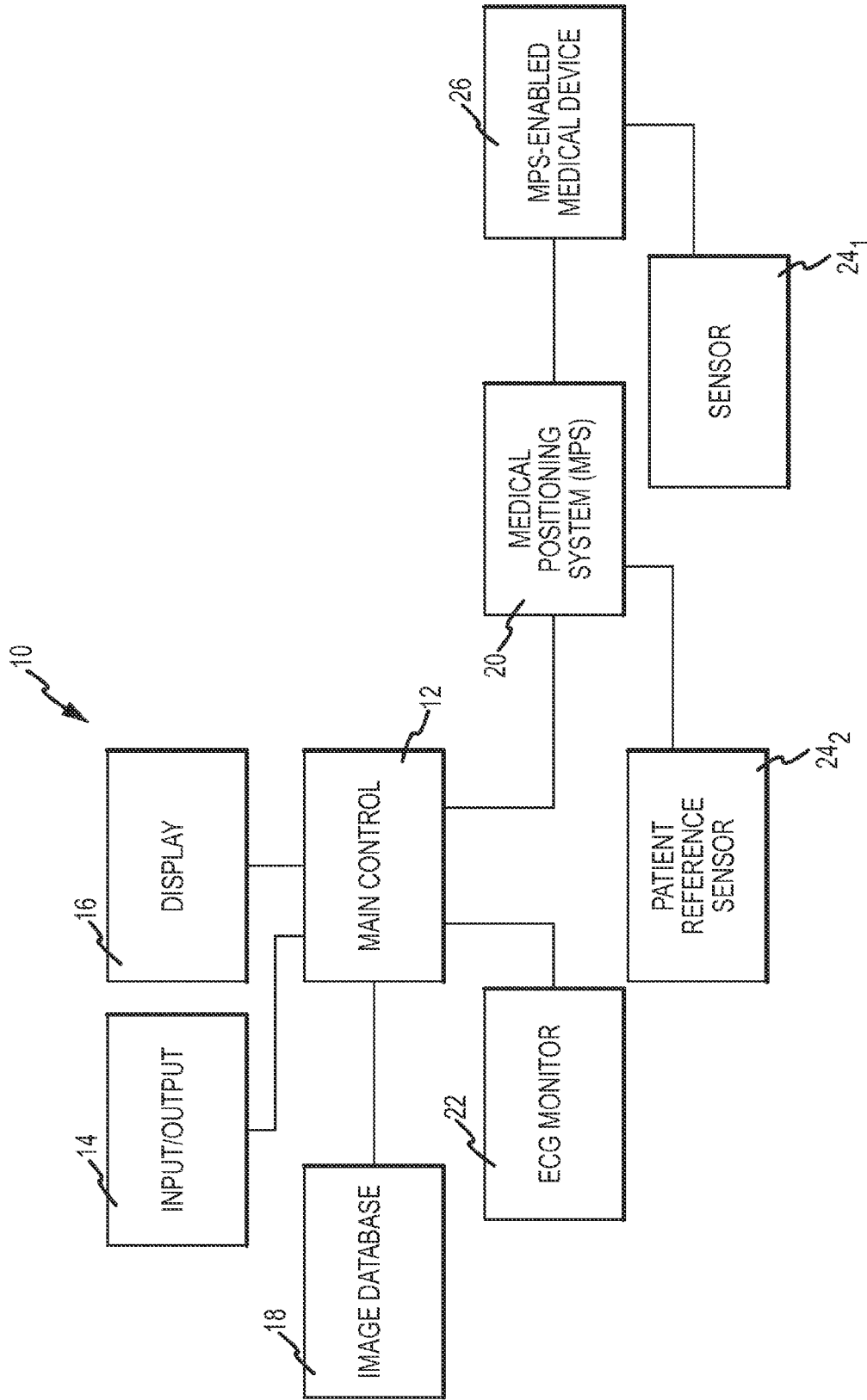


FIG.1

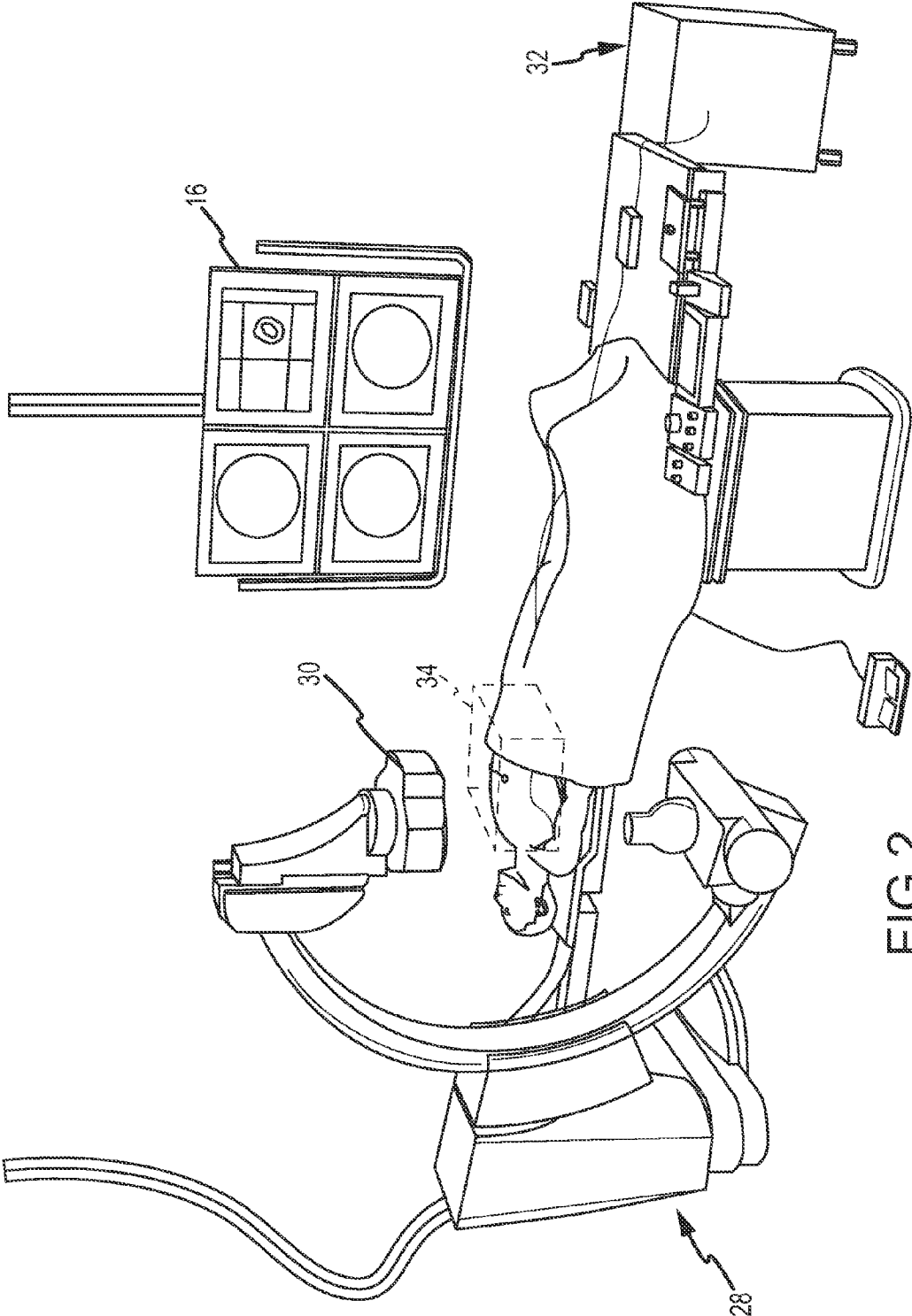


FIG.2

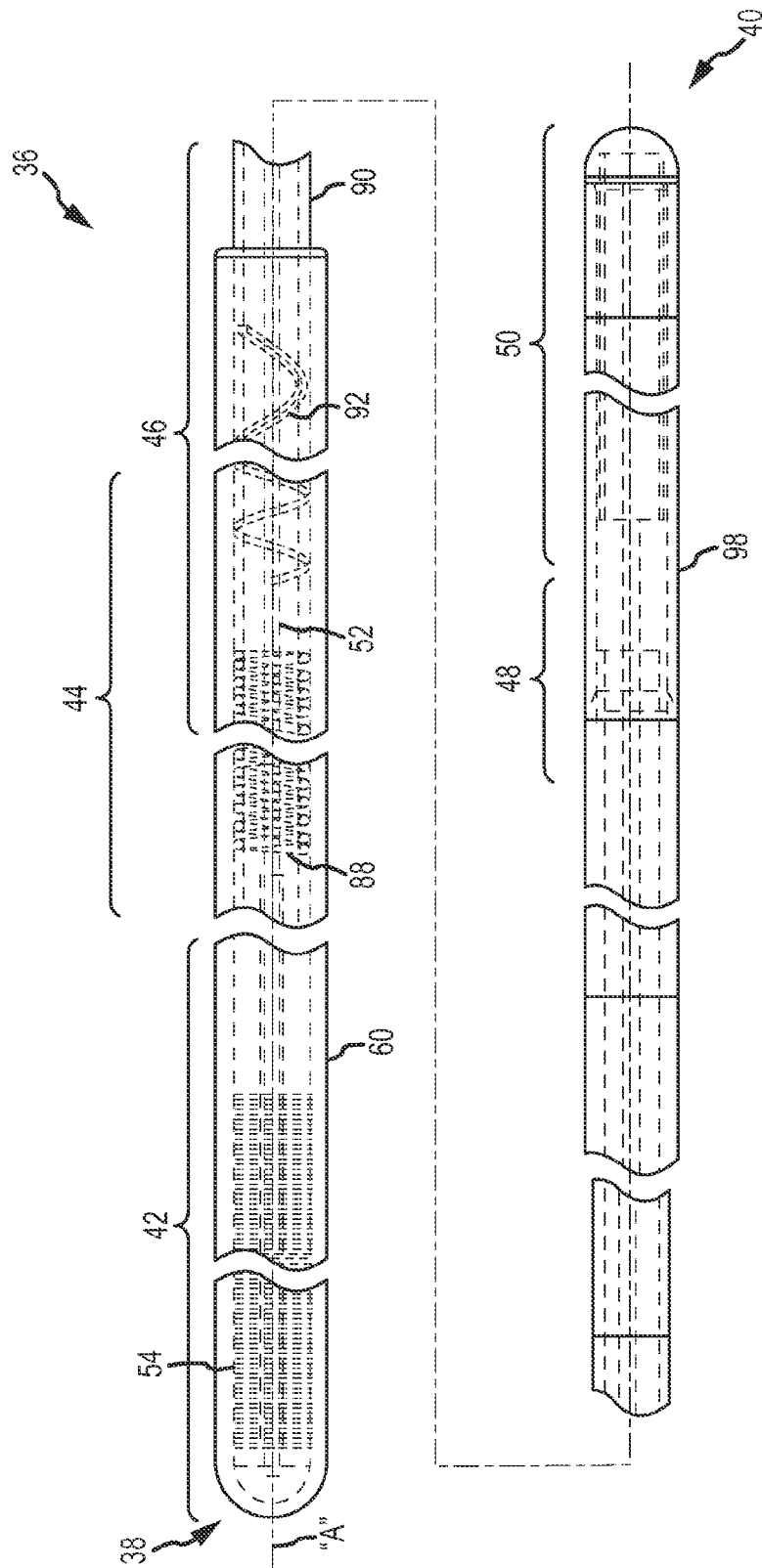


FIG.3

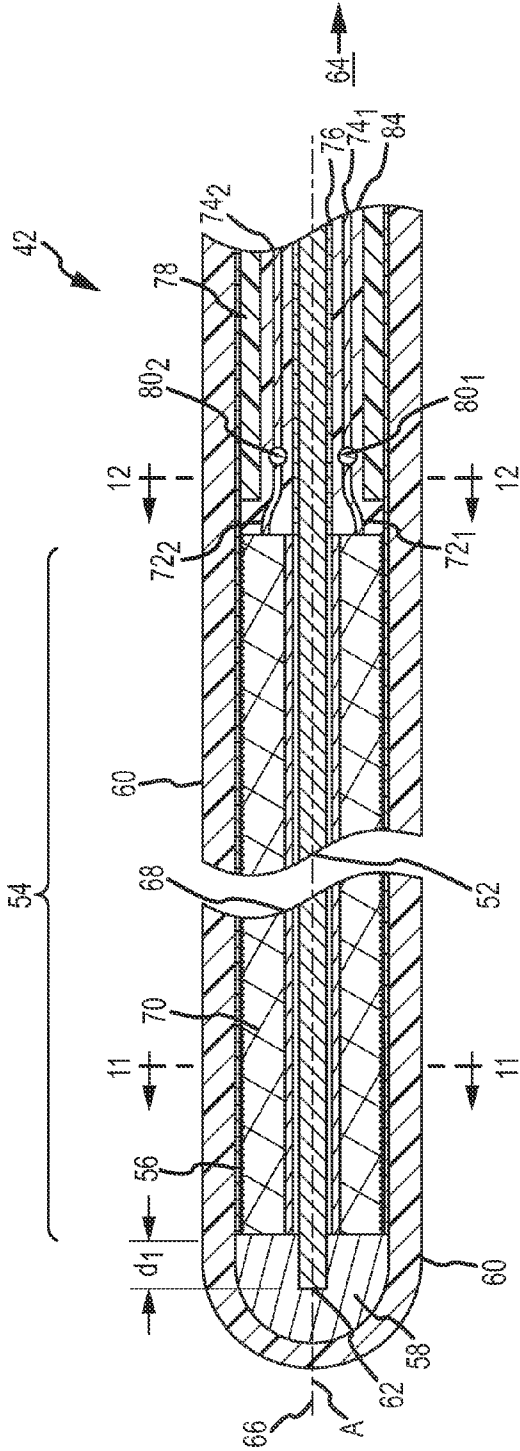


FIG. 4

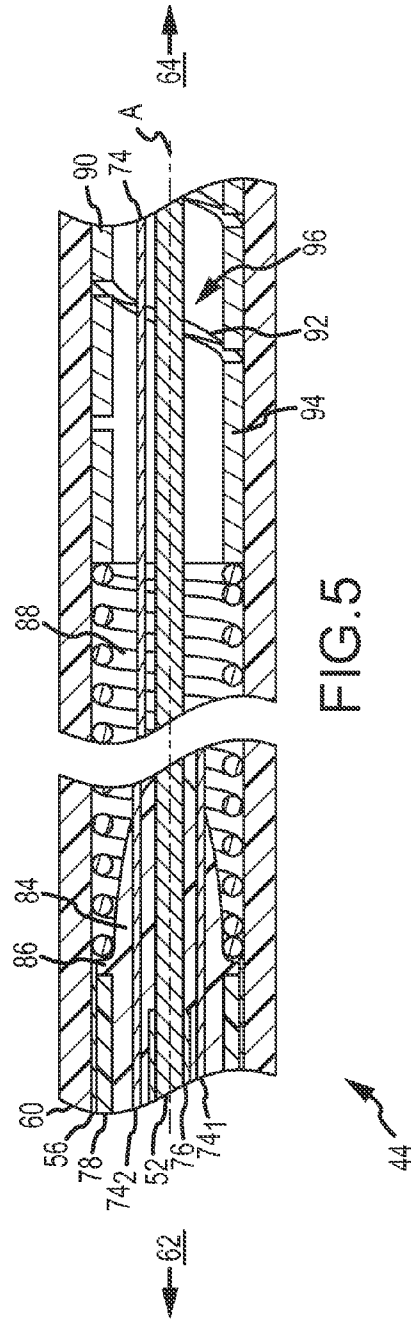


FIG. 5

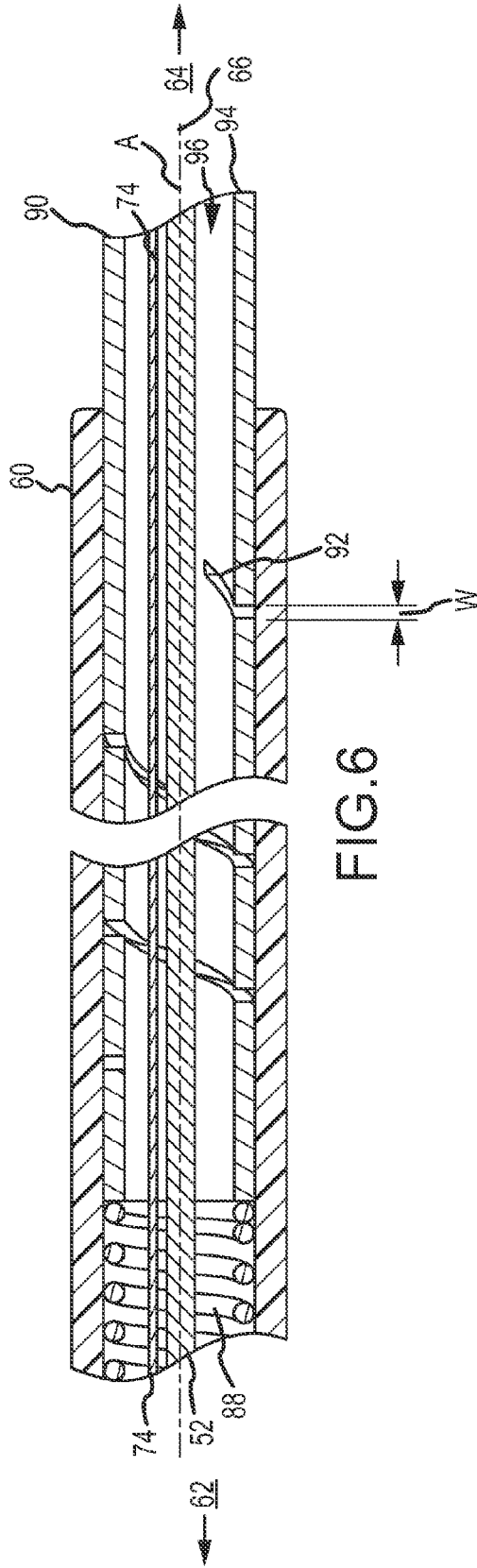


FIG. 6

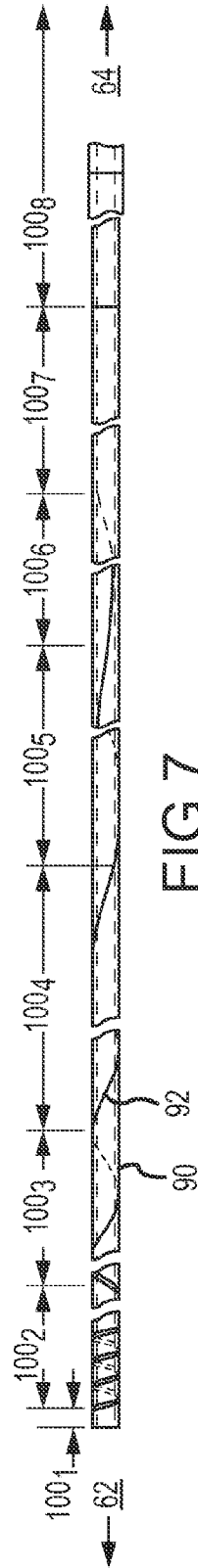
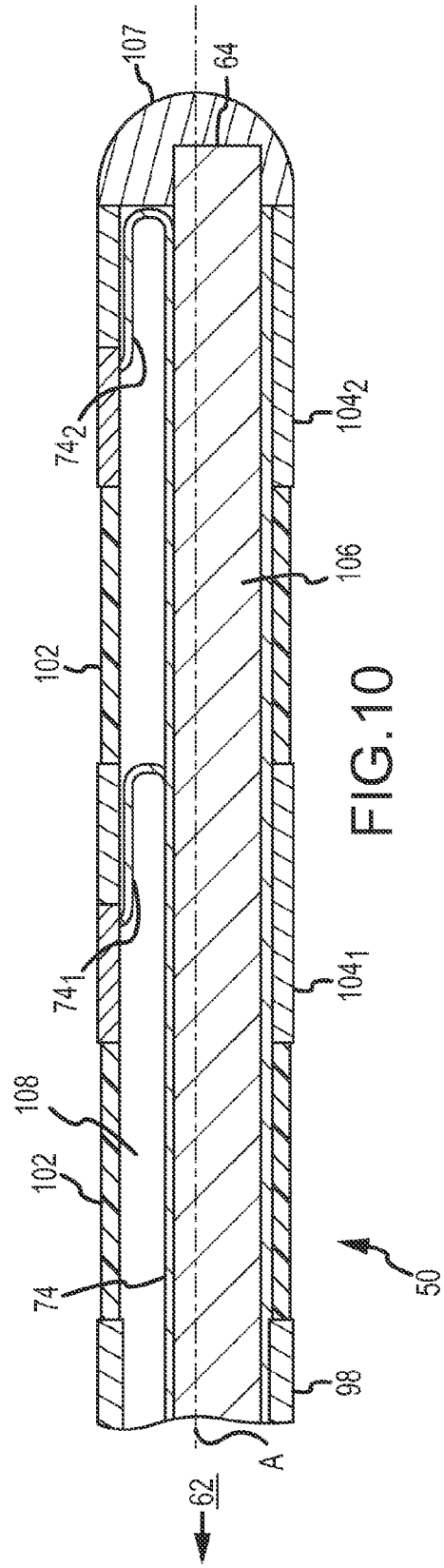
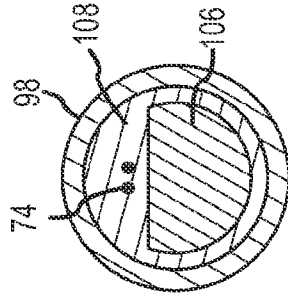
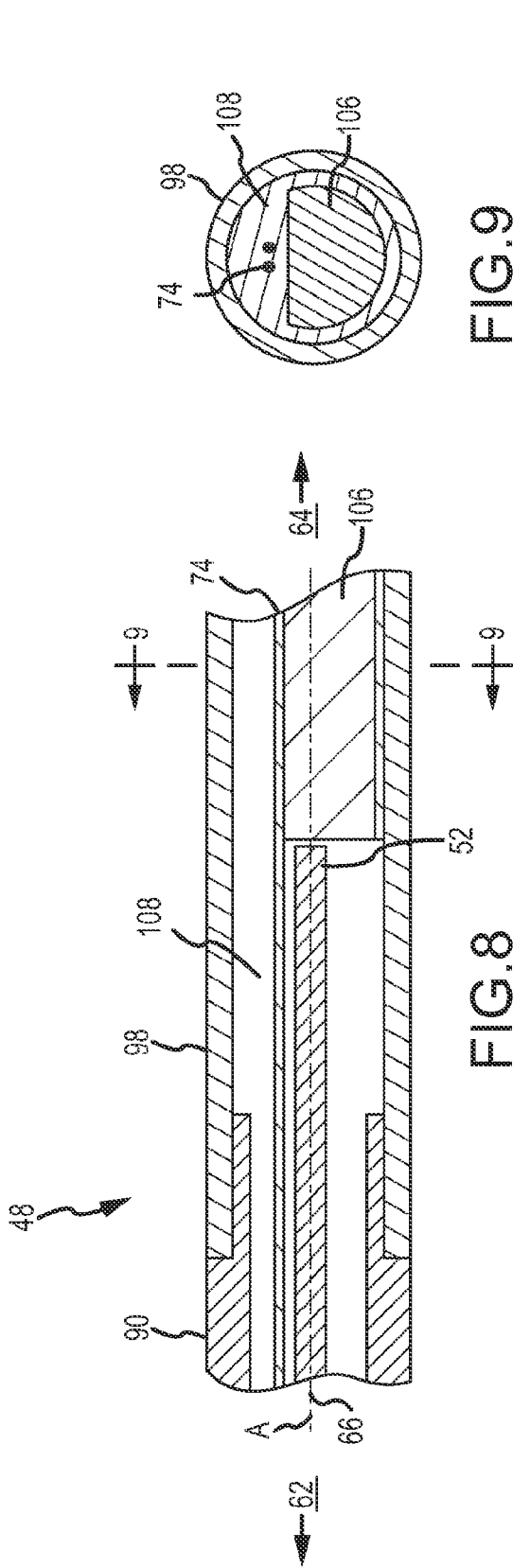


FIG. 7



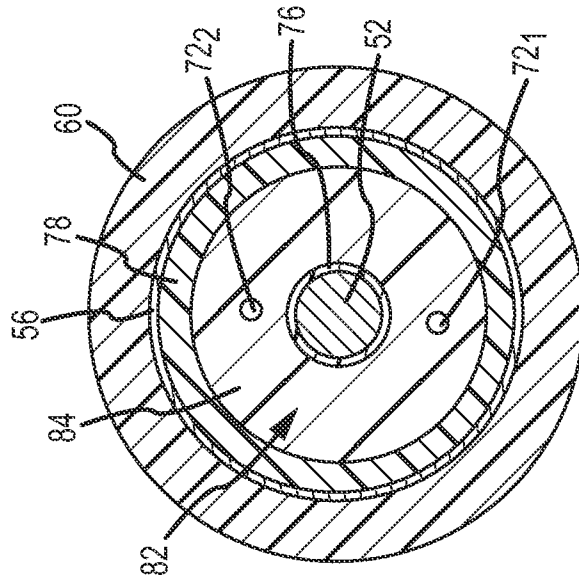


FIG.11

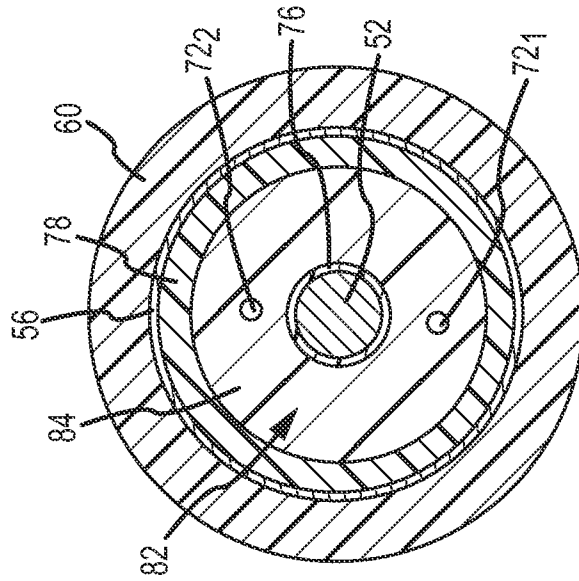


FIG.12

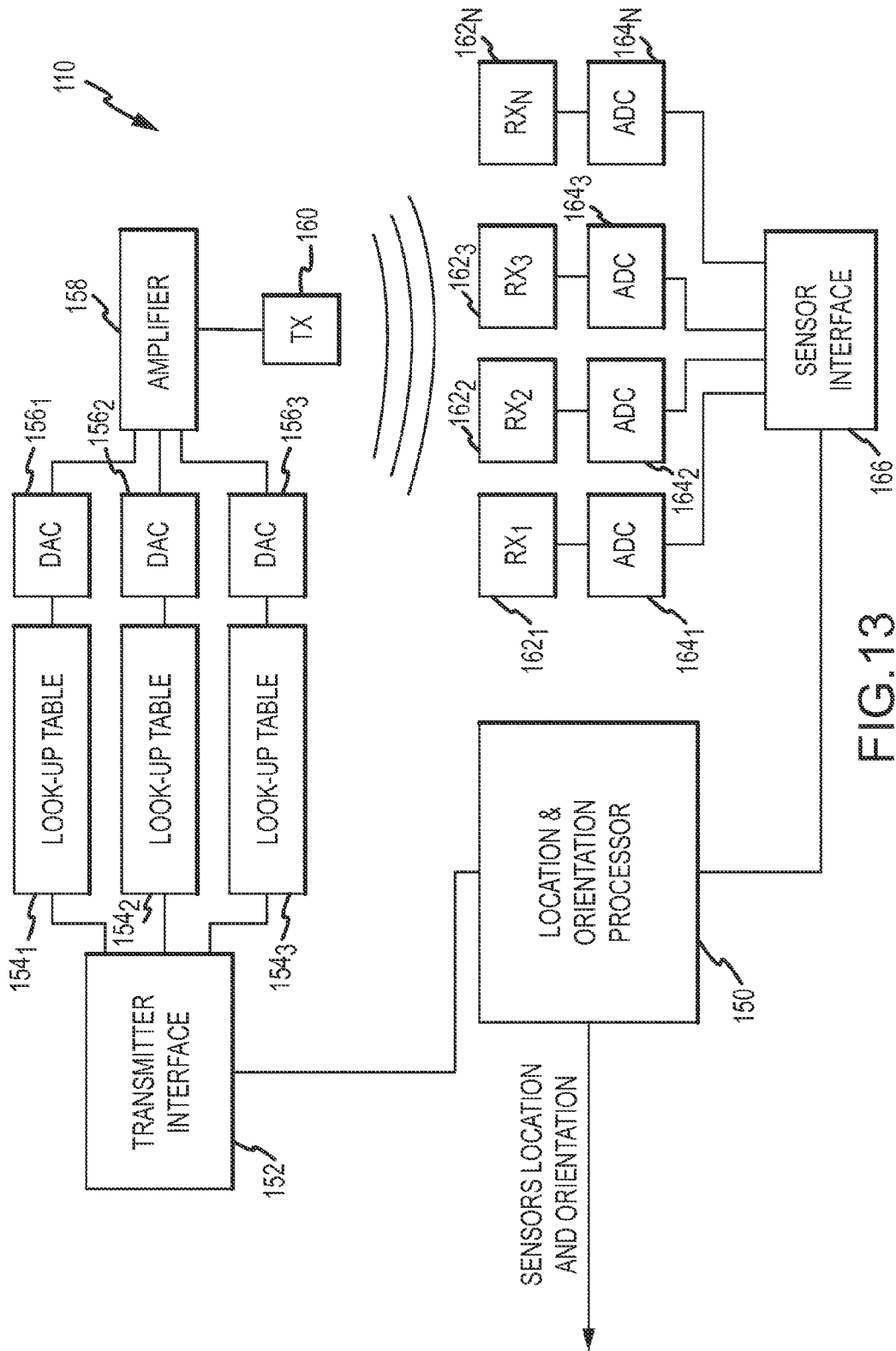


FIG.13

MEDICAL DEVICE GUIDEWIRE WITH HELICAL CUTOUT AND COATING

BACKGROUND OF THE INVENTION

a. Field of the Invention

The instant disclosure relates generally to a medical device guidewire, and more specifically to a medical device guidewire with a position sensor.

b. Background Art

Various diagnostic and therapeutic procedures in or on the body of a patient, such as in the circulatory system, the gastrointestinal tract, the brain vessels, the bronchial tree or the like may be performed or facilitated by inserting a catheter into a body lumen and thereafter navigating the diagnostic or therapeutic catheter to the target anatomical site. To facilitate navigation of the catheter, a guidewire is often used. The guidewire typically has a reduced diameter relative to the catheter; the reduced diameter aids a physician in inserting and navigating the guidewire to the anatomical site. The catheter is then passed over the guidewire and guided to the target site.

One method for maneuvering a guidewire involves the use of fluoroscopy to track the position of a guidewire, particularly its distal tip, during navigation. Another method of maneuvering a guidewire to an operational site is to place one or more position sensors on the guidewire, track the sensors with a navigation system, and display a real-time or rendered image of the guidewire for the clinician manipulating the guidewire to view. One such system for maneuvering a guidewire is detailed in published European Patent Application No. 09152619.4 filed 23 Jan. 2009, and published in English on 5 Aug. 2009 under publication no. EP2 085 108 A2, which is hereby incorporated by reference as though fully set forth herein.

Repeated contact between the tip of the guidewire and anatomical features of the patient during navigation is inevitable. Such contact can place unwanted stress on the structure of the guidewire and potentially damage the guidewire. To reduce instances of contact while maneuvering a guidewire to a target anatomical region, it is desirable for a clinician to be able to “see” the extreme distal tip of the guidewire. Accordingly, in embodiments where the guidewire is tracked by a navigation and positioning system, it is desirable to place a position sensor as close to the distal tip of the guidewire as possible. Moreover, regardless of the location of the position sensors on the guidewire, it is also desirable to protect the position sensor(s) and associated wiring from bending-induced stress as well as from exposure to body fluids to ensure reliable electrical function of the sensors. In addition, in the situation where the guidewire is used in delivering a cardiac pacing lead, it would be desirable that the guidewire be configured to be mechanically and electrically compatible with the lead.

There is therefore a need for an improved guidewire that minimizes or eliminates one or more problems as set forth above.

BRIEF SUMMARY OF THE INVENTION

In an embodiment, a guidewire may comprise an elongate body, a proximal connector assembly, a corewire, and a sensor assembly. The elongate body comprises a proximal and distal end portions. The body further has an annular wall that defines an interior lumen. The proximal connector assembly may be coupled to the proximal end portion of the body. The proximal connector assembly may be configured for connection to a medical positioning system. The corewire may have proximal and distal end portions. The corewire may extend through the lumen of the elongate body. The sensor assembly may be located on the distal end portion of the corewire and distal of the elongate body. The sensor assembly may be electrically connected by a pair of electrical conductors to the proximal connector assembly. The sensor assembly may be configured to generate an electrical signal indicative of at least a position of the sensor assembly in a reference coordinate system defined in the medical positioning system. The annular wall of the elongate body may include a helical cutout extending over a predetermined length of the distal end portion of the elongate body. The helical cutout may be configured to increase the flexibility over the predetermined length of the distal end portion of the body.

In an embodiment, a guidewire may comprise an elongate body, a proximal connector assembly, a corewire, a sensor assembly, and an outer coating. The elongate body comprises a proximal and distal end portions. The body further has an annular wall that defines an interior lumen. The proximal connector assembly may be coupled to the proximal end portion of the body. The proximal connector assembly may be configured for connection to a medical positioning system. The corewire may have proximal and distal end portions. The corewire may extend through the lumen of the elongate body. The sensor assembly may be located on the distal end portion of the corewire and distal of the elongate body. The sensor assembly may be electrically connected by a pair of electrical conductors to the proximal connector assembly. The sensor assembly may be configured to generate an electrical signal indicative of at least a position of the sensor assembly in a reference coordinate system defined in the medical positioning system. The outer coating may be radially-outwardly of at least the sensor assembly and may comprise an elastomer material. The outer coating may be configured to surround the distal end portion of the corewire and the sensor assembly. The coating may have a substantially continuous outer surface with a substantially uniform outside diameter along an axial length thereof.

The foregoing and other aspects, features, details, utilities, and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic and block diagram view of a system incorporating an embodiment of a guidewire.

FIG. 2 is a diagrammatic view of an exemplary catheter-lab environment in which the system of FIG. 1, particularly including the Medical Positioning System (MPS) enabled guidewire, may be used.

FIG. 3 is a diagrammatic view of an embodiment of a guidewire.

FIG. 4 is a cross-sectional side view of a portion of the guidewire of FIG. 3.

FIG. 5 is a cross-sectional side view of a portion of the guidewire of FIG. 3.

FIG. 6 is a cross-sectional side view of a portion of the guidewire of FIG. 3.

FIG. 7 is a diagrammatic side view of a portion of a body of the guidewire of FIG. 3, illustrating a helical cutout on the body.

FIG. 8 is a cross-sectional side view of a portion of the guidewire of FIG. 3.

FIG. 9 is a circumferential cross-sectional view of the guidewire of FIG. 8, taking substantially along line 9-9.

FIG. 10 is a cross-sectional side view of a portion of the guidewire of FIG. 3.

FIG. 11 is a circumferential cross-sectional view of the guidewire of FIG. 4, taking substantially along line 11-11.

FIG. 12 is a circumferential cross-sectional view of the guidewire of FIG. 4, taking substantially along line 12-12.

FIG. 13 is a schematic and block diagram view of one exemplary embodiment of a medical positioning system (MPS) as shown in block form in FIG. 1.

DETAILED DESCRIPTION OF THE INVENTION

Various embodiments are described herein to various apparatuses, systems, and/or methods. Numerous specific details are set forth to provide a thorough understanding of the overall structure, function, manufacture, and use of the embodiments as described in the specification and illustrated in the accompanying drawings. It will be understood by those skilled in the art, however, that the embodiments may be practiced without such specific details. In other instances, well-known operations, components, and elements have not been described in detail so as not to obscure the embodiments described in the specification. Those of ordinary skill in the art will understand that the embodiments described and illustrated herein are non-limiting examples, and thus it can be appreciated that the specific structural and functional details disclosed herein may be representative and do not necessarily limit the scope of the embodiments, the scope of which is defined solely by the appended claims.

Reference throughout the specification to “various embodiments,” “some embodiments,” “one embodiment,” or “an embodiment,” or the like, means that a particular feature, structure, or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, appearances of the phrases “in various embodiments,” “in some embodiments,” “in one embodiment,” or “in an embodiment,” or the like, in places throughout the specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments. Thus, the particular features, structures, or characteristics illustrated or described in connection with one embodiment may be combined, in whole or in part, with the features, structures, or characteristics of one or more other embodiments without limitation given that such combination is not illogical or non-functional.

It will be appreciated that the terms “proximal” and “distal” may be used throughout the specification with reference to a clinician manipulating one end of a medical device or instrument used to treat a patient. The term “proximal” refers to the portion of the device closest to the clinician and the term “distal” refers to the portion located furthest from the clinician. It will be further appreciated that for conciseness and clarity, spatial terms such as “vertical,” “horizontal,” “up,” and “down” may be used herein with respect to the illustrated embodiments. However, medical devices may be used in many orientations and positions, and these terms are not intended to be limiting or absolute.

Referring now to the drawings wherein like reference numerals are used to identify identical components in the various views, FIG. 1 is a block diagram view of a system 10 in which a position sensing guidewire may be used. System 10 as depicted includes a main electronic control unit 12 (e.g., including one or more electronic processors) having various input/output mechanisms 14, a display 16, an optional image database 18, a localization system such as a medical positioning system (MPS) 20, an electrocardiogram (ECG) monitor

22, one or more MPS location sensors respectively designated 24₁ and 24₂, and an MPS-enabled guidewire 26 which itself includes one and optionally more MPS location sensors, shown in exemplary fashion as having one such sensor 24₁.

Input/output mechanisms 14 may comprise conventional apparatus for interfacing with a computer-based control unit, for example, a keyboard, a mouse, a tablet, a foot pedal, a switch or the like. Display 16 may also comprise conventional apparatus.

Embodiments consistent with the instant disclosure may find use in navigation applications that use imaging of a region of interest. Therefore system 10 may optionally include image database 18. Image database 18 may be configured to store image information relating to the patient's body, for example, a region of interest surrounding a destination site for medical device 26 and/or multiple regions of interest along a navigation path contemplated to be traversed by device 26 to reach the destination site. The image data in database 18 may comprise known image types including (1) one or more two-dimensional still images acquired at respective, individual times in the past; (2) a plurality of related two-dimensional images obtained in real-time from an image acquisition device (e.g., fluoroscopic images from an x-ray imaging apparatus, such as that shown in exemplary fashion in FIG. 2) wherein the image database acts as a buffer (live fluoroscopy); and/or (3) a sequence of related two-dimensional images defining a cine-loop (CL) wherein each image in the sequence has at least an ECG timing parameter associated therewith adequate to allow playback of the sequence in accordance with acquired real-time ECG signals obtained from ECG monitor 22. It should be understood that the foregoing are examples only and not limiting in nature. For example, the image database 18 may also include three-dimensional image data as well. It should be further understood that the images may be acquired through any imaging modality, now known or hereafter developed, for example X-ray fluoroscopy, ultra-sound, computerized tomography, nuclear magnetic resonance or the like.

MPS 20 is configured to serve as the localization system and therefore to determine positioning (localization) data with respect to one or more of MPS location sensors 24_i (where i=1 to n) and output a respective location reading. The location readings may each include at least one or both of a position and an orientation (P&O) relative to a reference coordinate system, which may be the coordinate system of MPS 20. For example, the P&O may be expressed as a position (i.e., a coordinate in three axes X, Y and Z) and orientation (i.e., an azimuth and elevation) of a magnetic field sensor in a magnetic field relative to a magnetic field generator(s) or transmitter(s).

MPS 20 determines respective locations (i.e., P&O) in the reference coordinate system based on capturing and processing signals received from the magnetic field sensors 24_i while such sensors are disposed in a controlled low-strength AC magnetic field (see FIG. 2). From an electromagnetic perspective, these sensors develop a voltage that is induced on the sensing coil residing in a changing magnetic field, as contemplated here. Sensors 24_i are thus configured to detect one or more characteristics of the magnetic field(s) in which they are disposed and generate an indicative signal, which is further processed by MPS 20 to obtain a respective P&O thereof. Exemplary design features and manufacturing processes and methods for sensors 24_i and medical devices incorporating such sensors are known in the art.

MPS sensor 24₁, and optionally additional MPS sensors in further embodiments, may be associated with MPS-enabled medical device 26. Another MPS sensor, namely, patient ref-

erence sensor (PRS) **24₂** (if provided in system **10**) is configured to provide a positional reference of the patient's body so as to allow motion compensation for gross patient body movements and/or respiration-induced movements. PRS **24₂** may be attached to the patient's manubrium sternum, a stable place on the chest, or another location that is relatively positionally stable. Like MPS location sensor **24₁**, PRS **24₂** is configured to detect one or more characteristics of the magnetic field in which it is disposed wherein MPS **20** provides a location reading (e.g., a P&O reading) indicative of the PRS's position and orientation in the reference coordinate system.

The electro-cardiogram (ECG) monitor **22** is configured to continuously detect an electrical timing signal of the heart organ ("organ timing signal") through the use of a plurality of ECG electrodes (not shown), which may be externally-attached to the outside of a patient's body. The timing signal generally corresponds to the particular phase of the cardiac cycle, among other things. Generally, the ECG signal(s) may be used by the control unit **12** for ECG synchronized playback of a previously captured sequence of images (cine loop) stored in database **18**. ECG monitor **22** and ECG-electrodes may both comprise conventional components.

FIG. **2** is a diagrammatic view of system **10** as incorporated into a larger system, namely, a catheter lab. More specifically, the system **10** is shown as being incorporated into an fluoroscopic imaging system **28**, which may include commercially available fluoroscopic imaging components. It should be understood that while embodiments may be used in the catheter-lab environment to be described below, this is exemplary only and not limiting in nature. MPS **20** includes a magnetic transmitter assembly (MTA) **30** and a magnetic processing core **32** for determining location (P&O) readings. MTA **30** is configured to generate the magnetic field(s) in and around the patient's chest cavity, in a predefined three-dimensional space identified as a motion box **34**. MPS sensors **24**, as described above are configured to sense one or more characteristics of the magnetic field(s) and when the sensors are in motion box **34**, each generate a respective signal that is provided to magnetic processing core **32**. Processing core **32** is responsive to these detected signals and is configured to calculate respective P&O readings for each MPS sensor **24**, in motion box **34**. Thus, MPS **20** enables real-time tracking of each sensor **24**, in three-dimensional space.

The positional relationship between the image coordinate system and the MPS reference coordinate system may be calculated based on a known optical-magnetic calibration of the system (e.g., established during setup), since the positioning system and imaging system may be considered fixed relative to each other in such an embodiment. However, for other embodiments using other imaging modalities, including embodiments where the image data is acquired at an earlier time and then imported from an external source (e.g., imaging data stored in database **18**), a registration step registering the MPS coordinate system and the image coordinate system may need to be performed so that MPS location readings can be properly coordinated with any particular image being used. One exemplary embodiment of an MPS **20** will be described in greater detail below in connection with FIG. **13**.

FIG. **3** is a diagrammatic view, with portions broken away, of a guidewire **36** that may be used as the medical device **26** in system **10** (FIG. **1**). FIG. **3** shows guidewire **36** in a completed state of assembly and several components thereof will be identified before proceeding to the remainder of the detailed description. Guidewire **36** is generally elongate and extends along a central longitudinal axis designated "A" between a guidewire distal end **38** and a guidewire proximal end **40**.

The guidewire **36** includes a sensor assembly **54** (i.e., best shown in FIG. **4**) having an output signal useful for position detection. As shown, the sensor assembly **54** is very close to the extreme distal end **38**, and hence provides very accurate indication of the location of the distal tip, for example, for intra-body navigation.

The guidewire **36** further includes an elastomeric coating **60** (i.e., best shown in FIG. **4**) whose uniform outside diameter (OD), smooth outer surface is particularly useful for delivering cardiac pacing leads, which fit over coating **60** without entanglement.

The guidewire **36** further includes a body **90** (e.g., tube, best shown in FIG. **7**) having a helical cut out **92** (i.e., best shown in FIG. **7**) whose pitch decreases towards distal end **38**, thus increasing the flexibility of body **90** towards distal end **38**. The increase in flexibility improves navigability.

The proximal end of tube **90** is ground (i.e., reduced outside diameter) so as to permit mechanical coupling to a proximal connector assembly **98**. The proximal connector assembly **90** also provides electrical connectivity between the guidewire (i.e., in particular the sensor assembly **54**) and external equipment, such as MPS **20**.

The guidewire **36** further includes a central corewire **52** (i.e., best shown in FIGS. **4-6** and **8**) extending generally from proximal connector assembly **98** to the extreme distal plug of guidewire **36**. The corewire **52** provides improved mechanical properties of the guidewire **36**. For descriptive purposes only, guidewire **36** may have a first portion **42**, a second portion **44**, a third portion **46**, a fourth portion **48**, and a fifth portion **50**. Each portion will be described in further detail below.

FIG. **4** is a diagrammatic, cross-sectional side view showing the distal end of guidewire **36** in greater detail (i.e., first portion **42**), with portions broken away. FIGS. **11** and **12** are cross-sectional views taken along lines **11-11** and **12-12**, respectively, in FIG. **4**. Guidewire **36** includes central corewire **52**, sensor assembly **54**, a shroud **56**, a plug **58**, and a coating **60**.

Corewire **52** is configured to distribute bending stresses, tensile loads, and compressive loads over its length, reducing stress on the other components of guidewire **36**, such as the wiring that electrically connects sensor assembly **54** to the proximal connector assembly **98**. In other words, loads (e.g., due to contact with tissue) imposed on shroud **56** are transferred via coating **60** to plug **58** to corewire **52**, and similarly loads directly imposed on coating **60** to plug **58** are likewise resolved through corewire **52**. Corewire **52** contributes to the overall mechanical properties of the guidewire **36**.

Corewire **52** is located substantially at the radial center of guidewire **36**. In other words, a central longitudinal axis **66** of corewire **52** is substantially the same as or coincident with central axis "A" of guidewire **36**. Corewire **52** has a distal end portion which, in the illustrated embodiment, generally coincides with guidewire distal end **38**, and is at least as co-extensive as the axial extent of shroud **56**. An extreme distal end **62** of corewire **52** may be flush with or may extend distally a distance d_1 past the distal end of the sensor assembly **54**, being situated substantially in the central region of plug **58**. In distal end portion, corewire **52** has a circular cross-section of constant diameter (best seen in FIGS. **11-12**). Corewire **52** further includes a proximal end portion **64**, as seen in FIG. **8**.

In an embodiment, corewire **52** may be made of metal, such as stainless steel, titanium, or nickel titanium alloys (i.e., NITINOL), or other biocompatible material. In an embodiment, corewire **52** may be a single continuous wire extending substantially the entire axial length of guidewire **36** (i.e., form

proximal connector **98** to plug **58**), which may provide the benefit of distributing bending stresses over the entire length of guidewire **36**. In another embodiment (not shown), corewire **52** may be a multi-piece construction, such as the construction described in U.S. patent application Ser. No. 12/359,010 filed 23 Jan. 2009, hereby incorporated by reference as though fully set forth herein.

The illustrated embodiment of corewire **52** is intended to be exemplary only and not limiting. Many variations could be made to corewire **52** and still fall within the spirit and scope of the present disclosure. For example, corewire **52** may comprise a material other than metal and may have a non-circular cross-section. Additionally, corewire **52** may be solid, hollow, or have some other interior construction.

Sensor assembly **54** is configured to detect one or more characteristics of a magnetic field in which it is disposed and produce an output electrical indicative thereof. The output signal, as described above (see description relating to sensor **24**) can be processed by MPS **20** to produce a location of the sensor assembly **54**. The location can include at least one or both of the position and orientation of the sensor assembly **54** in a reference coordinate system. In an embodiment, sensor assembly **54** may be substantially similar or the same as the sensor assembly described in U.S. application Ser. No. 12/980,848 filed 29 Dec. 2010, hereby incorporated by reference as though fully set forth herein.

Sensor assembly **54** is located radially-outwardly from corewire **52** and may comprise multiple elements, or may be unitary. In the illustrated embodiment, sensor assembly **54** comprises a hollow cylindrical sensor core **68** with a wire **70** wound on sensor core **68** to form a sensor coil with two free ends thereof forming a pair of sensor leads **72₁**, **72₂** which are available at a proximal end of sensor assembly **54**. Sensor core **68** may be a tube comprising magnetically permeable material, with the tube having a central lumen, where corewire **52** passes through the central lumen.

A clearance **73** may exist between an inner diameter of sensor core **68** and outer diameter of corewire **52**, as seen in FIG. **11**. Clearance **73** may be filled with an insulating material, such as epoxy, which secures sensor core **68** to corewire **52** and insulates sensor core **68** from corewire **52**. Sensor core **68** may comprise magnetically-permeable material which increases the overall sensitivity of the sensor core/sensor coil combination **68**, **70** that forms positioning sensor assembly **54** (as compared to the same coil configuration without a magnetically-permeable core). In an embodiment, sensor core **68** may be made of a metal alloy of magnetically-permeable material, such as an alloy of nickel and iron.

In an embodiment, when sensor core **68** is secured (e.g., via epoxy) to the distal end portion of corewire **52**, corewire **52** may additionally act as a safety wire. In the event that any portion of guidewire **36** is structurally compromised (e.g., body **90** is fractured), the bond between corewire **52** and sensor assembly **54** maintains the structural integrity with the extreme distal end portion **62** of guidewire **36**. The bond between corewire **52** and sensor assembly **54** acts as a safety feature allowing for extraction of the extreme distal end of guidewire **36** from the patient. In an embodiment, corewire **52** may additionally be secured to the proximal end of guidewire **36**, such as bonding proximal end portion **64** of corewire **52** to proximal connector assembly **98** using an adhesive **108** (e.g. epoxy), and the safety feature of corewire **52** may be maintained from distal end to proximal end of guidewire **36**.

As described above, a function of sensor assembly **54**, in the context of a magnetic field based positioning system, is to detect one or more characteristics of the magnetic field(s) in which sensor assembly **54** is placed. In this regard, one of

ordinary skill in the art will appreciate there are many variations and configurations of sensor assembly **54**. For example and without limitation, while sensor assembly **54** is shown in the distal end portion of guidewire **36**, the position of sensor assembly **54** and/or position of a plurality of sensor assemblies **54** may be located throughout guidewire **36** and such variations and configurations remain within the spirit and scope of the present disclosure.

With continued reference to FIG. **4**, guidewire **36** may further comprise a wire cable **74**, an insulator tube **76**, and an alignment tube **78**. Wire cable **74** may comprise a first wire **74₁** and a second wire **74₂**. First wire **74₁** and second wire **74₂** may be twisted together, forming a twisted pair along a substantial length of wire cable **74**. For example, for the substantial portion of the axial length of guidewire **36**, starting from proximal connector assembly **98** and extending distally towards sensor assembly **54**, the wires **74₁**, **74₂**, remain twisted, as shown in FIG. **5**. The twisting of the wires improves noise reduction, as known. However, as the wire cable **74** approaches sensor assembly **54**, the two wires **74₁**, **74₂** are separated (i.e., untwisted) in order to allow respective electrical connection to the two free ends of sensor coil **70**.

In this regard, sensor leads **72₁**, **72₂** are conductively connected to wire cable **74** at connection nodes **80₁**, **80₂**. As shown, sensor lead **72₁** may be conductively connected (i.e., electrically connected) to first wire **74₁** at connection node **80₁**, and sensor lead **72₂** may be conductively connected to second wire **74₂** at connection node **80₂**.

Insulator tube **76** is configured to electrically isolate corewire **52** from the other electrically active components at the distal end of guidewire **36**. In this regard, sensor leads **72₁**, **72₂**, connection nodes **80₁**, **80₂**, and a portion of wire cable **74** are electrically insulated from corewire **52** by insulator tube **76**. In an embodiment, insulator tube **76** may be a polymer tube, such as, but not limited to, polyimide, that is slipped onto corewire **52**. Alternatively, insulator tube **76** may comprise a heat-activated "shrink" tube comprising electrically insulating material. In a further embodiment, insulator tube **76** may be a layer of polymer that is sprayed onto or otherwise applied to corewire **52**, or some other electrically insulating structure on corewire **52**.

Alignment tube **78** is configured to provide mechanical protection for the sensor assembly/twisted pair connections (i.e., connections **80₁**, **80₂**), particularly from externally-imposed forces encountered during use (e.g., contacting body/tissue structures). One failure mode for a guidewire of the type including such electrical connections is the disconnection or failure of the electrical connection at one or both of **80₁**, **80₂**. The alignment tube **78** helps mitigate this problem. In addition, alignment tube **78** is configured to provide a uniform outside diameter structure onto which shroud **56** can conform. Alignment tube **78** thus also provides a manufacturing function.

The alignment tube **78** is located proximal of the sensor assembly **54** and distal of the coil **88**. Alignment tube **78** may have an outside diameter that is approximately the same as the outside diameter of the sensor assembly **54**, and have an inside diameter that is large enough to enclose at least the connections **80₁**, **80₂** that the tube **78** is configured to protect. Alignment tube **78** may comprise a polymer tube comprising, for example only, polyimide material or the like.

Referring to FIG. **12**, alignment tube **78** includes an interior space, designated space **82** that is large enough to accommodate sensor leads **72₁**, **72₂**, connection nodes **80₁**, **80₂**, and a portion of wire cable **74**, which are routed therethrough. In an embodiment, space **82** may ultimately be filled with a nonconductive epoxy material **84**. Epoxy material **84**, when

cured, provides mechanical protection for sensor leads 72₁, 72₂, connection nodes 80₁, 80₂, and a portion of wire cable 74. Epoxy material 84 also bonds insulator tube 76, sensor leads 72₁, 72₂, connection nodes 80₁, 80₂, a portion of wire cable 74, sensor core 68, sensor coil 70, a portion of shroud 56, a portion of corewire 52, and coil 88 together.

Referring to FIGS. 4-5 and FIGS. 11-12, shroud 56 is configured to provide a smooth, substantially continuous cylindrical sub-assembly to which the corewire 52 can be bonded (i.e., provides a potting volume). In addition, shroud 56 may provide some measure of protection to the interior components of the distal assembly from compressive and tensile loads resulting from insertion, removal, and bending of guidewire 36. The shroud 56 comprises a tube that directly covers the outer circumferential surfaces of sensor assembly 54, alignment tube 78, and a portion of epoxy material 84. A distal end of shroud 56 may be aligned with the distal end of sensor assembly 54 and the distal end of shroud 56 may be adjacent to a proximal end of plug 58. Shroud 56 may be a polymer shrink tube or another electrically insulating structure or material. For example only, shroud 56 may comprise polyethylene terephthalate (PET) material, although shroud 56 may comprise materials other than PET. The illustrated embodiment of shroud 56 is exemplary only, and should not be construed as limiting. Although shroud 56 is shown as a thin-walled tube of substantially constant diameter, shroud 56 may have another shape or cross-section, which may be constant or may vary along its axial length.

Plug 58 is provided at the extreme distal end of guidewire 36 for structural support and to provide for non-traumatic contact of the extreme distal end of guidewire 36 when introducing and navigating the guidewire through a lumen of a patient. Plug 58 is preferably rounded and may be made of polymer, glue, bonding material, metal, or any other relatively smooth material suitable for this purpose. Plug 58 is shown in a hemispherical shape, but may be in any other non-traumatic form. Plug 58 may be coupled to one or more of corewire 52, sensor assembly 54, and shroud 56 by gluing, bonding, welding, soldering, or another patient-safe coupling method.

FIGS. 5-6 and 8 are cross-sectional side views, with portions broken-away, of second portion 42, third portion 44, fourth portion 46 of guidewire 36. FIG. 7 is a diagrammatic side view of a body 90 having a helical cutout 92. As seen in FIGS. 5-8, guidewire 36 may further comprise coil 88, body 90, and helical cutout 92.

Coil 88 is configured to provide bending flexibility as well as, in an embodiment, radiopacity by virtue of material selection. In this regard, coil 88 may comprise radiopaque material (e.g., metal), such as platinum, to increase fluoroscopic visibility. Coil 88 may also be made of stainless steel, iridium, or nickel titanium alloys (i.e., NITINOL). In addition to providing flexibility and fluoroscopic visibility, coil 88 also protects cable wiring 74 that is proximally located with respect to shroud 56. The proximal end of coil 88 may be soldered to tube 90 while the distal end of coil 88 may be bonded to sensor assembly 54 by conventional methods (e.g., with an adhesive such as medical grade epoxy, or with another patient-safe (biocompatible) coupling method).

Body 90, which may comprise a flexible elongate hollow tube that allows the passage of electrical wiring therethrough. Body 90 thus includes an annular wall 94 defining a central lumen 96 configured to provide sufficient space for the electrical wiring as well as the corewire 52, while at the same time having a minimum impact on the torque transfer and structural characteristics of the guidewire 36. As described above, corewire 52 and cable wiring 74 run throughout lumen 96.

As best shown in FIG. 8, the proximal end of body 90 is attached to proximal connector assembly 98. The proximal end of body 90 may be ground down (i.e., reduced outside diameter), for example as a taper or as a step or shoulder, to facilitate attachment to connector assembly 98. As shown in FIG. 8, the reduced outside diameter of body 90 corresponds to the inside diameter of the distal end portion of proximal connector body 98, thereby allowing a low-clearance fit or interference fit.

As best shown in FIG. 3, body 90 may have variable outside diameter along various portions of body 90. For example, in an embodiment, the outside diameter of the distal portion of body 90 may be smaller than the outside diameter of the proximal portion of body 90. This difference in outside diameter may be seen by comparison of the two distal-most tube portions in FIG. 3 (i.e., the proximal portion of tube 90 has a greater outside diameter than the adjacent distal portion). The reduced outside diameter along the distal portion of body 90 provides radial space for coating 60 without the resultant outside diameter exceeding a preferred maximum outside diameter of guidewire 36.

In an embodiment, the progressively decreasing outside diameter of body 90 (as taken in the distal direction) may be achieved by reducing the thickness of annular wall 94 by known methods. For example, one known method may involve grinding down or drawing down the outer surface of annular wall 94. Through the foregoing, the inside diameter of body 90 remains the same, but the thickness of annular wall 94 along the distal portion of body 90 is reduced, thereby also reducing the outside diameter thereof. In an embodiment, the reduced thickness of annular wall 94 may extend approximately ten inches from the distal end of body 90 toward the proximal end of body 90. The reduction in thickness of annular wall 94 may be performed in steps, or may be a gradual transition. The reduced thickness of the body may be used to design a preferred amount of flexibility of body 90. In an embodiment, body 90 may be made of metal. When body 90 is metal, it may be connected to an electrical ground and act as electrical interference shielding for wire cable 74 passing through lumen 96 of body 90.

Body 90 is provided with a helical cutout 92 to configure body 90 with greater or lesser levels of flexible in predefined areas. Helical cutout 92, in an embodiment, involves completely removing wall material from annular wall 94. In an embodiment, helical cutout 92 may extend substantially from the distal end of body 90 for a predetermined axial length, spiraling proximally towards the proximal end of body 90. In one embodiment, the pitch, which may be defined as the axial distance corresponding to one revolution of the helix, is substantially constant. In another embodiment, however, the pitch varies as a function of axial position from the distal end of body 90.

Referring to FIG. 7, body 90 is provided with helical cutout 92 that has a progressively increasing pitch as the helical cutout 92 extends away from the distal end of body 90 toward the proximal end of body 90. For example, in a first interval 100₁ (distal-most portion of body 90) no helical cutout 92 is provided on body 90. In second, third, fourth, fifth, sixth and seventh intervals 100₂-100₇, respectively, the pitch along body 90 (axially) either increases or is maintained. An eighth interval 100₈ of body 90 does not incorporate a helical cutout 92. The lower the pitch, the more flexible body 90 will be in that interval. In the illustrated embodiment, body 90 will be most flexible along distal end and gradually become less flexible (e.g., more stiff) as helical cutout 92 moves proximally. In an embodiment, the pitch of helical cutout 92 may transition gradually. In an embodiment, the tube 90 may be

hypo tube stock, and where the helical cutout **92** may be formed using laser cutting or other methods known in the art. Although one particular detailed width of helical cutout **92** has been provided, it is appreciated that other widths may be used to control the amount of flexibility as desired, and other widths not provided in detail remain within the spirit and scope of the present disclosure.

Coating **60** creates a smooth, continuous, substantially uniform outside diameter surface which is advantageous in some medical applications, such as delivering pace-maker leads and other implantable device leads. For example, the nature of the outer surface of coating **60** acts as a lubricant of sorts with an inside diameter of such leads, preventing lock up of the inside diameter surface of the leads with the outside diameter surface of sensor assembly **54** and coil **88**. Coating **60** is a radially outermost hyperelastic polymeric layer disposed on distal portion of guidewire **36**. Coating **60** may be a relatively soft and flexible material, such as a polyurethane elastomer commercially available under the trade designation PELLETHANE, from The Lubrizol Corporation, Wickliffe, Ohio, USA. In a PELLETHANE material embodiment, the material used for coating **60** may have a hardness of about 55 D (durometer). In another embodiment, the material used for coating **60** may have a hardness range of about 35 D to 65 D. It should be understood, however, that other materials may be used for coating **60**, such as a thermoplastic elastomer available under the trade designation SANTOPRENE available from ExxonMobil Chemical Company, Houston, Tex., USA.

Coating **60** completely circumferentially surrounds plug **58** and extends proximally over body **90** to approximately the point where the taper of body **90** begins. Thus, coating surrounds shroud **56**, coil **88**, helical cutout **92** and a portion of body **90**. Coating **60** completely covers helical cutout **92**, and therefore seals what would otherwise be an opening into body **90** caused by helical cutout **92**. Coating **60** advantageously seals the distal end portion of guidewire **36**, rendering the distal end portion of guidewire **36** watertight. Coating **60** may be hydrophilic or hydrophobic, and may have an overcoat of hydrophilic coating material. In an embodiment, the maximum outermost diameter of coating **60** does not exceed a maximum outermost diameter at any point along the entire guidewire **36**. In an embodiment, coating **60** may have a thickness such that a maximum outer diameter of the guidewire **36** may be 0.0140 inches to 0.0145 inches. This may be advantageous in allowing a pacing lead to pass over the entire length of guidewire **36**.

FIGS. **9-10** are cross-sectional views of an embodiment of fifth portion **50** of guidewire **36**. FIG. **9** is a circumferential cross-sectional view of proximal connector assembly **98**. FIG. **10** is a diagrammatic cross-sectional side view of proximal connector assembly **98**.

In an embodiment, proximal connector assembly **98** may be substantially similar to a connector assembly described in U.S. Pat. No. 8,109,889, hereby incorporated by reference as though fully set forth herein. Connector assembly **98** is a bending resistant male-type connector disposed on the proximal end of guidewire **36** configured to conductively engage a female-type connector that is operatively connected to medical positioning system **20**. Electric signals from sensor assembly **54** are communicated to the MPS **20** for determining a location reading of the sensor assembly **54**, as described above.

In an embodiment, connector assembly **98** may comprise a plurality of insulator sleeves **102**, a plurality of conductor rings **104**, and a D-shaped pin **106**. D-shaped pin **106** is positioned in a lumen of connector assembly **98**, as shown in FIG. **9**. A distal end of D-shaped pin **106** is attached to

proximal end of corewire **52** using adhesive **108** (e.g., epoxy). A proximal end of D-shaped pin **106** is attached to a proximal tip **107**. D-shaped pin **106** may provide additional structure to connector assembly **98** as well as clearance for wire cable pass through the lumen of connector assembly **98**. A first wire **74₁** of wire cable **74** is conductively connected to a first conductor ring **104₁**. A second wire **74₂** of wire cable **74** is conductively connected to a second conductor ring **104₂**. The distal end of connector assembly **98** is attached to a reduced diameter of the proximal end portion of body **90**. Insulator sleeves **102** are positioned adjacent to conductor rings **104**. The lumen of connector assembly **98** may be filled with an insulating material, such as epoxy, which may secure D-shaped pin **106**, wire cable **74**, insulator sleeves **102**, and conductor rings **104** to connector assembly **98**. The insulating material may also provide additional rigidity for connector assembly **98**.

A method of manufacturing an embodiment of guidewire **36** will now be set forth. Coil **88** is soldered to the distal end of body **90**. Next, insulator tube **76** is placed onto corewire **52** (distal end) and then trimmed to length. Corewire **52** is bonded to sensor assembly **54** (e.g., using epoxy). The larger alignment tube **78** is then slid on over corewire **52** and cable **74**. Once the leads **72** from sensor assembly **54** have been soldered to the distal end leads from wiring **74**, then alignment tube **78** is slid into place over solder joints **80**. Shroud **56** (e.g., shrink tube) is then placed over sensor assembly **54** and alignment tube **78**. Epoxy is introduced into cavity **73** (i.e., interior of the shrink tube), using known means (e.g., a needle). Heat is applied, which shrinks shrink tube **56** to the outside diameter of sensor assembly **54** and alignment tube **78**, but also cures the epoxy. An additional dab of epoxy is applied to the distal end of guidewire **36**, including corewire **52**, thereby forming hemispherical plug **84**. From the proximal end of body **90** of guidewire **36**, wiring **74** (twisted pair) is pulled through for alignment at the proximal end. Body **90** is slid distally and body **90** (i.e., the distal portion of coil **88**) is adhered (e.g., epoxy) to sensor assembly **54** (see detail FIG. **5**). The electrical connections between wiring **74** and proximal connector assembly **98** are made. Corewire **52** is also bonded to proximal connector assembly **98**. The coating **60** is applied.

FIG. **13** is a schematic and block diagram of one exemplary embodiment of MPS **20**, designated as a MPS **110**, as also seen by reference to U.S. Pat. No. 7,386,339, referred to above, and portions of which are reproduced below, which generally describes, at least in part, the MediGuide™ medical positioning system commercially offered by MediGuide Ltd. of Haifa, Israel and now owned by St. Jude Medical, Inc. It should be understood that variations are possible, for example, as also seen by reference to U.S. Pat. No. 6,233,476, hereby incorporated by reference as though fully set forth herein. Another exemplary magnetic field-based MPS is the Carto™ system commercially available from Biosense Webster, and as generally shown and described in, for example, U.S. Pat. No. 6,498,944 (the '944 patent), and U.S. Pat. No. 6,788,967 (the '967 patent), both hereby incorporated by reference as though fully set forth herein. Accordingly, the following description is exemplary only and not limiting in nature.

MPS system **110** includes a location and orientation processor **150**, a transmitter interface **152**, a plurality of look-up table units **154₁**, **154₂** and **154₃**, a plurality of digital to analog converters (DAC) **156₁**, **156₂** and **156₃**, an amplifier **158**, a transmitter **160**, a plurality of MPS sensors **162₁**, **162₂**, **162₃** and **162_N**, a plurality of analog to digital converters (ADC) **164₁**, **164₂**, **164₃** and **164_N** and a sensor interface **166**.

Transmitter interface **152** is connected to location and orientation processor **150** and to look-up table units **154₁**, **154₂** and **154₃**. DAC units **156₁**, **156₂** and **156₃** are connected to a respective one of look-up table units **154₁**, **154₂** and **154₃** and to amplifier **158**. Amplifier **158** is further connected to transmitter **160**. Transmitter **160** is also marked TX. MPS sensors **162₁**, **162₂**, **162₃** and **162_N** are further marked RX₁, RX₂, RX₃ and RX_N, respectively. Analog to digital converters (ADC) **164₁**, **164₂**, **164₃** and **164_N** are respectively connected to sensors **162₁**, **162₂**, **162₃** and **162_N** and to sensor interface **166**. Sensor interface **166** is further connected to location and orientation processor **150**.

Each of look-up table units **154₁**, **154₂** and **154₃** produces a cyclic sequence of numbers and provides it to the respective DAC unit **156₁**, **156₂** and **156₃**, which in turn translates it to a respective analog signal. Each of the analog signals is respective of a different spatial axis. In the present example, look-up table **154₁** and DAC unit **156₁** produce a signal for the X axis, look-up table **154₂** and DAC unit **156₂** produce a signal for the Y axis and look-up table **154₃** and DAC unit **156₃** produce a signal for the Z axis.

DAC units **156₁**, **156₂** and **156₃** provide their respective analog signals to amplifier **158**, which amplifies and provides the amplified signals to transmitter **160**. Transmitter **160** provides a multiple axis electromagnetic field, which can be detected by MPS sensors **162₁**, **162₂**, **162₃** and **162_N**. Each of MPS sensors **162₁**, **162₂**, **162₃** and **162_N** detects an electromagnetic field, produces a respective electrical analog signal and provides it to the respective ADC unit **164₁**, **164₂**, **164₃** and **164_N** connected thereto. Each of the ADC units **164₁**, **164₂**, **164₃** and **164_N** digitizes the analog signal fed thereto, converts it to a sequence of numbers and provides it to sensor interface **166**, which in turn provides it to location and orientation processor **150**. Location and orientation processor **150** analyzes the received sequences of numbers, thereby determining the location and orientation of each of the MPS sensors **162₁**, **162₂**, **162₃** and **162_N**. Location and orientation processor **150** further determines distortion events and updates look-up tables **154₁**, **154₂** and **154₃**, accordingly.

It should be understood that system **10**, particularly the main electronic control unit **12**, as described above may include conventional processing apparatus known in the art, capable of executing pre-programmed instructions stored in an associated memory, all performing in accordance with the functionality described herein. Such an electronic control unit may further be of the type having both ROM, RAM, a combination of non-volatile and volatile (modifiable) memory so that any software may be stored and yet allow storage and processing of dynamically produced data and/or signals.

Although only certain embodiments have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this disclosure. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected/coupled and in fixed relation to each other. Additionally, the terms “electrically connected” and “in communication” are meant to be construed broadly to encompass both wired and wireless connections and communications. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting. Changes in

detail or structure may be made without departing from the invention as defined in the appended claims.

Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

What is claimed is:

1. A guidewire comprising:

an elongate body formed from a tube including proximal and distal end portions, said elongate body further including an annular wall that defines an interior lumen; a proximal connector assembly coupled to said proximal end portion of said elongate body, said proximal connector assembly being configured for connection to a medical positioning system;

a corewire including proximal and distal end portions, said corewire extending through said lumen;

a sensor assembly located on said distal end portion of said corewire and distal of said elongate body, said sensor assembly being electrically connected by a pair of electrical conductors to said proximal connector assembly, said sensor assembly being configured to generate an electrical signal indicative of at least a position of said sensor assembly in a reference coordinate system defined in said medical positioning system;

wherein said annular wall of said elongate body includes a continuous helical cutout of a uniform width extending over a predetermined length of said distal end portion of said elongate body and around an axis of the elongate body a plurality of revolutions, said continuous helical cutout being configured to increase the flexibility over said predetermined length of said distal end portion of said elongate body, and wherein an axial distance corresponding to each of the plurality of revolutions of the continuous helical cutout decreases towards a distal end of the elongate body.

2. The guidewire of claim **1** further including a plug coupled with said distal end portion of said corewire wherein said plug has a distal, non-traumatic tip portion.

3. The guidewire of claim **1** wherein said sensor assembly and said pair of electrical conductors are electrically connected at a pair of connection nodes, further including:

an alignment tube proximal of said sensor assembly configured in size to enclose said connection nodes, to thereby protect said connection nodes from external forces.

4. The guidewire of claim **1** wherein said sensor assembly has a first outside diameter and said alignment tube has a second outside diameter, said first and second outside diameters being substantially equal.

5. The guidewire of claim **1**, further comprising a coil positioned between a proximal end of said sensor assembly and a distal end of said elongate body, said coil comprising radio-opaque material.

6. The guidewire of claim **1** wherein said corewire extends through said sensor assembly, said corewire being affixed to said sensor assembly wherein said corewire is operative as a safety wire.

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7. The guidewire of claim 1 further comprising an outer coating radially-outwardly of at least said sensor assembly and comprising elastomer material, said outer coating configured to surround said distal end portion of said corewire and said sensor assembly, and said outer coating including a substantially continuous outer surface with a substantially uniform outside diameter along an axial length thereof.

8. The guidewire of claim 7 wherein said axial length of said outer coating is configured to extend over said predetermined length of said helical cutout.

9. The guidewire of claim 7 further comprising a shroud surrounding said sensor assembly, wherein said outer coating directly contacts said shroud and a portion of said elongate body, and said outer coating renders said distal end portion of said guidewire watertight.

10. The guidewire of claim 1, further comprising:

a coil positioned proximally with respect to the sensor assembly, the coil being coaxial with the axis of the elongate body; and

an alignment tube disposed between the sensor assembly and the coil, the alignment tube being coaxial with the axis of the elongate body.

11. The guidewire of claim 10, wherein an outer diameter of the sensor assembly, the alignment tube, and the coil are uniform.

12. The guidewire of claim 11, wherein a shroud surrounds the sensor assembly, the alignment tube, and the coil.

13. A guidewire comprising:

an elongate body formed from a tube including proximal and distal end portions, said elongate body further including an annular wall that defines an interior lumen, wherein the annular wall includes a continuous helical cutout that extends over a length of the distal end portion of the elongate body and around an axis of the elongate body a plurality of revolutions, wherein an axial distance corresponding to each of the plurality of revolutions of the continuous helical cutout decreases towards a distal end of the elongate body;

a proximal connector assembly coupled to said proximal end portion of said elongate body, said proximal connector assembly being configured for connection to a medical positioning system;

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a corewire including proximal and distal end portions, said corewire extending through said lumen;

a sensor assembly located on said distal end portion of said corewire and distal of said elongate body, said sensor assembly being electrically connected by a pair of electrical conductors to said proximal connector assembly, said sensor assembly being configured to generate an electrical signal indicative of at least a position of said sensor assembly in a reference coordinate system defined in said medical positioning system; and

an outer coating radially-outwardly of at least said sensor assembly and comprising an elastomer material, said outer coating configured to surround said distal end portion of said corewire and said sensor assembly, said outer coating including a substantially continuous outer surface with a substantially uniform outside diameter along an axial length thereof.

14. The guidewire of claim 13 wherein said outer coating comprises a polyurethane elastomer.

15. The guidewire of claim 14 wherein said polyurethane elastomer has a durometer hardness in a range of about 35D-65D.

16. The guidewire of claim 13 wherein said outer coating is hydrophilic.

17. The guidewire of claim 13 wherein said outer coating has a substantially constant thickness.

18. The guidewire of claim 13 wherein said substantially uniform outside diameter of said outer coating is equal or less than a maximum outside diameter of both said elongate body and said proximal connector assembly.

19. The guidewire of claim 13 further comprising a tubular coil positioned between a proximal end of said sensor assembly and a distal end of said elongate body, wherein said tubular coil is covered by said outer coating.

20. The guidewire of claim 13 further comprising a shroud surrounding said sensor assembly, wherein said outer coating is directly contacting said shroud, said coil, and a portion of said elongate body, and said outer coating renders said distal end portion of said guidewire watertight.

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